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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,245	12/18/2001	Yoshiaki Fukuda	46/224	8337

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WASHINGTON, DC 20036-3307

EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/018,245

Applicant(s)

FUKUDA ET AL.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/18/01
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This application appears to be in compliance with the Sequence Rules.
2. Applicant's amendment, filed 12/18/01, is acknowledged.  
Claims 7 and 9 have been amended.  
Claims 11-13 have been added (not amended as indicated in the amendment).

Claims 1-13 are pending.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claims 1-2, 9-10, 13, drawn to H chain polypeptides of anti-TNFalpha antibodies, anti-TNFalpha antibodies comprising said H chains and compositions thereof.

Group II, claims 1-2, 9-10, 12 drawn to L chain polypeptides of anti-TNFalpha antibodies, anti-TNFalpha antibodies comprising said L chains and compositions thereof

Group III, claims 5, 7, 8, drawn to genes, expression vectors and methods of producing H chain polypeptides of anti-TNFalpha antibodies

Group IV, claims 6, 8, 11 drawn to genes, expression vectors and methods of producing L chain polypeptides of anti-TNFalpha antibodies

4. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups I-IV were found to have no special technical feature that defined the contribution over the prior art of Nagahira et al. (J. Immunol. Methods 222: 83-92 (1999), Nagahira et al. Immuno. Lett. 64 : 139-144 (1998) and Hirai et al. (J. Immunol. Methods 96: 57-62 (1987) as set forth in International Search Report provided in the instant application.

Accordingly, Groups I-IV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept that defines a contribution over the prior art.

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5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

(A) With respect to Groups I and III, this application contains claims directed to the following patentably distinct species of the claimed Invention: wherein the anti-TNFalpha antibody comprises at least one of :

- (i) CDR-H1 (SEQ ID NO: 1),
- (ii) CDR-H2 (SEQ ID NO: 2), or
- (iii) CDR-H3 (SEQ ID NO: 3).

These species are distinct because their structures and physicochemical properties differ.

B) With respect to Groups II and IV,

This application contains claims directed to the following patentably distinct species of the claimed Invention: wherein the anti-TNFalpha antibody comprises at least one of :

- (i) CDR-L1 (SEQ ID NO: 4),
- (ii) CDR-L2 (SEQ ID NO: 5), or
- (iii) CDR-L3 (SEQ ID NO: 6).

These species are distinct because their structures and physicochemical properties differ.

(C) Alternatively, applicant is invited to consider the following

Applicant is required to elect a particular anti-TNFalpha antibody and to provide the following information with respect to the elected species of anti-TNFalpha antibody:

- i) applicable CDR-H1, CDR-H-2 and CDR-H-3 heavy chain SEQ ID NOS.,
- ii) applicable CDR-L1, CDR-L-2 and CDR-L-3 light chain SEQ ID NOS., or
- iii) applicable CDR-H1, CDR-H-2 and CDR-H-3 heavy chain SEQ ID NOS CDR sequences AND applicable CDR-L1, CDR-L-2 and CDR-L-3 light chain SEQ ID NOS.

These species of anti-TNFalpha antibodies are distinct because each antibody possess a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen binding site.

If applicant decides to elect according to (iii) by electing a series of CDRs for the heavy chain and a series of CDRs for the light chain, then Groups I and II would be rejoined and Groups III and IV would be rejoined.

It is noted that a functional antibody would require all three CDRs for a heavy and light chain. By choosing a sufficient number of CDRs for a functional antibody, applicant avoids possible issues under 35 USC 112, first paragraph, enablement.

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6. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, PhD.  
Primary Examiner  
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September 29, 2004